

REMARKS

Claims 1-41 are pending in the application. Claims 25-40 have been withdrawn. Claims 4, 10 and 19 have been cancelled. Claims 42-44 have been added. Support for claim 42 is found at page 11, lines 15 to 20. Support for claims 43-44 is found at page 11, lines 3 to 14 and page 16, lines 9 to 19. Claims 1, 8, 9 and 18 have been amended. Support for the amendments is found at page 9, line 22 to page 10, line 6. No new matter has been introduced by the amendments.

Claim Rejections 35 U.S.C. § 102

Claims 1, 4, 5, 7-11, 16-20, 23 and 24 have been rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Application 2002/0050220 to Schueller et al. Schueller discloses a deformable stamp that can be coated with a transferable material that can be transferred to a substrate. The transferable material can include a polymer, a solvent and an agent that could be therapeutic. It is the position of the Examiner that Schueller teaches the invention as presently claimed. This is not the case.

Nowhere does Schueller teach or suggest a "...tubular implantable medical device...supported on a mandrel..." as recited in claims 1, 9 and 18 of the present invention. The Examiner does suggest that Schueller teaches that "...the tubular stent is supported by end tubing, i.e., mandrel." The Examiner has mis-read and mis-interpreted the reference. Schueller teaches that "Each end of the stamp 10 is attached to a length of tubing 44 to form an airtight seal" as disclosed at [0046] of Schueller. Schueller is not concerned with the substrate being positioned on the equivalent of a mandrel, rather the stamp is positioned on the equivalent of a mandrel. For this reason, the rejection of claims 1, 9 and 18, and claims 4,

5, 7, 8, 10, 11, 16, 17, 19, 20, 23 and 24 dependent thereon, as anticipated by Schueller should be withdrawn.

Claims 1, 4, 5, 9-11 and 41 have been rejected under 35 U.S.C. § 102(b) as anticipated by Research Disclosure Database Number 434009 entitled “Drug Loading Device for Drug Delivery or Coated Stent” (‘009). The ‘009 reference discloses a device positioned on a mandrel that is pre-coated with a polymer then rolled on a carrier, such as a cloth or sponge, that is soaked with a therapeutic agent solution or paste. The ‘009 reference further teaches that the device can be rolled along the inside wall of a cylindrical cup that contains along it’s wall a therapeutic agent soaked carrier. It is the position of the Examiner that ‘009 teaches the invention as presently claimed. Applicants respectfully disagree.

The ‘009 reference does not teach or suggest rolling the device on an applicator that contains a polymer and a solvent, as recited in claims 1 and 9 of the present invention. Rather, ‘009 teaches that “The device (B) is pre-coated with a swell-loading or therapeutic agent specific “binding” polymer.” Then the device is rolled on a carrier that includes a therapeutic agent solution or paste. Because ‘009 does not teach or suggest a coating composition that contains both a polymer and a solvent, the rejection of claims 1 and 9, and claims 4, 5, 10 and 11 dependent thereon should be withdrawn.

With respect to claim 41, ‘009 does not teach or suggest “...submerging a portion of the tubular implantable medical device into a coating composition...and rotating the device along a longitudinal central axis of the device while the device is partially submerged in the coating composition.” Rather, ‘009 discloses that “The vessel device (B) is rolled along the inside wall of the therapeutic agent (D) soaked carrier (C) thereby loading the vessel device (B) with the therapeutic agent solution (D).” The ‘009 reference does state that the device can

be loaded with therapeutic agent solution by rotating the device in a cup (E) filled with therapeutic agent solution. However, the cup is not actually 'filled' with a liquid solution in which the device is submerged, as presently claimed, rather the cup is lined with therapeutic agent in a carrier, e.g., a sponge or foam type material. For these reasons, the rejection of claim 41 as anticipated by '009 should be withdrawn.

Claim Rejections 35 U.S.C. § 103

Claims 2, 3 and 6 have been rejected under 35 U.S.C. § 103(a) for obviousness over '009. The teachings and deficiencies of '009 are set forth above. The Examiner has taken the position that while '009 does not specifically teach the thickness of the coating layer on the applicator surface or the viscosity of the composition, both of these limitations would have been obvious to one having ordinary skill in the art. Whether these limitations would have been obvious or not is moot, since '009 does not teach or suggest rolling the device on an applicator that contains a polymer and a solvent as recited in claim 1. Thus, one skilled in the art would have had no reason whatsoever to look to '009 for guidance in teaching the present invention.

For the above reasons, the rejection of claims 2, 3 and 6 as obvious over '009 should be withdrawn.

Claims 9, 12-15 and 22 have been rejected under 35 U.S.C. § 103(a) for obviousness over Schueller in view of U.S. Patent No. 6,565,659 to Pacetti et al. (Pacetti). The teachings and deficiencies of Schueller are described above. Applicants have herein provided a declaration under 37 C.F.R. §1.131 of Stephen D. Pacetti showing conception and diligence in completing the invention of claims 9, 12-15 and 22 prior to the effective date of Pacetti. The

declaration indicates that the information disclosure statement on which the present application is based is commensurate in scope with claims 9, 12-15 and 22 and is evidence of conception prior to just before May 20, 2003, which antedates the priority date of Pacetti.

Therefore, Pacetti is unavailable as an anticipatory reference under 35 U.S.C. §102(a).

However, Pacetti would qualify as prior art under 35 U.S.C. § 102(e), therefore pursuant to 35 U.S.C. § 103(c), Pacetti is unavailable as prior art under 35 U.S.C. § 103(a) since the subject matter of Pacetti and the subject matter of the present invention were both subject to an obligation of assignment to Advanced Cardiovascular Systems, Inc. The assignment of the subject matter of the present invention to Advanced Cardiovascular Systems, Inc. was recorded at Reel 014597, Frame 0773 on October 7, 2003.

In view of the fact that Pacetti is unavailable as prior art, it cannot remedy the deficiencies of Schueller. Therefore, the rejection of claims 9, 12-15 and 22 for obviousness over Schueller in view of Pacetti should be withdrawn.

Claim 21 has been rejected under 35 U.S.C. § 103(a) for obviousness over Schueller. It is the position of the Examiner that it would have been obvious for one skilled in the art to rotate the applicator at between 0.1 rotations per minute to 200 rotations per minute. However, Schueller does not teach or suggest a "...tubular implantable medical device...supported on a mandrel..." as recited in claim 18 of the present invention. Therefore one skilled in the art would have had no reason whatsoever to look to Schueller for guidance in teaching the present invention.

For the above reasons, the rejection of claim 21 for obviousness over Schueller should be withdrawn.

Specification

As requested by the Examiner, applicants have amended the abstract to provide a more definitive abstract.

The Examiner has also indicated that Figure 1 should be designated by a legend such as "Prior Art". Applicant does not understand this objection since Figure 1 is already labeled Prior Art. The removal of this objection is therefore requested.

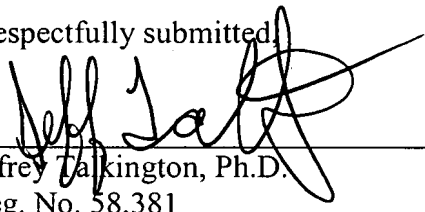
CONCLUSION

The Commissioner is authorized to charge the amount due to Squire, Sanders & Dempsey Deposit Account No. 07-1850.

Date: October, 29, 2007

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Respectfully submitted,



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